

REMARKS

Rejection under 35 U.S.C. §112, 2nd paragraph

Claims 28-34 have been rejected under 35 U.S.C. §112, 2nd paragraph as being indefinite with regard to recitation of “said disease”. Claims 28-34 have been amended to replace “said disease” to “said infection”, which finds proper antecedent basis in claims 25 and 26.

Rejections under 35 U.S.C. §102(b)

1) Nagaoka (JP ‘070) - Claims 14-23, 26, 27, 31 and 33 have been rejected as being anticipated under 35 U.S.C. §102(b) by Nagaoka (JP ‘070) with the U.S. equivalent U.S. 2004/0038330. Claims 14-23 and 33 have been cancelled, thus rendering this rejection moot with regard to these claims. Applicants traverse the rejection of claims 26, 27 and 31 and withdrawal thereof is respectfully requested.

Claims 26, 27 and 31 have been amended to exclude HIV infection. Support for this amendment may be found in the originally filed disclosure which included HIV infection. The Court of Customs & Patent Appeals, predecessor to the Court of Appeals for the Federal Circuit held in *In re Johnson and Farnham*, 194 USPQ 187 (Ct. Cust. & Pat. App. 1977) that support for a proviso added to a claim to exclude previously claimed subject matter is not new matter and finds support in the original disclosure of the subject matter. The court noted in *In re Johnson*,

“Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable.” It is for the inventor to decide what *bounds* of protection he will seek. *In re Saunders*, 58 CCPA 1316, 1327, 444 F.2d 599, 607, 170 USPQ 213, 220 (1971). To deny appellants the benefit of their grandparent application in this case would, as this court said in *Saunders*: “* * * let form triumph over substance, substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was first with the genus when he filed.”

Thus, the disclosure in the originally filed specification of HIV infection provides support the instant disclaimer by proviso of such subject matter.

JP '070 discloses only HIV as an infection. There is no disclosure of other infections, such as Hepatitis B. As noted the claims have been amended to exclude HIV infection; as such JP '070 does not anticipate the instant claimed invention. The present invention of claims 26, 27 and 31 is further not obvious over the disclosure of JP '070 because HIV is a retrovirus, which has a very different life cycle from other viruses, including hepatitis B virus. Withdrawal of the rejection is therefore respectfully requested.

2) Nagaoka JP '816 - Claims 14-18, 23, 26 and 27 have been rejected under 35 U.S.C. §102(b) as being anticipated by Nagaoka JP '816. Claims 14-18 and 23 have been cancelled, thus rendering the rejection moot with regard to these rejections. Applicants traverse the rejection of claims 23, 26 and 27 and withdrawal thereof is respectfully requested. JP '816 teaches the use of an extract of *Lentinus edodes* mycelium as a component for inhibiting melanin production and for promoting melanin hypochromicity. However, while JP '816 discloses the topical application of the extract to the skin for these purposes, there is no disclosure or suggestion in JP '816 of antibacterial or antiviral activity of an extract from *Lentinus edodes* mycelium. As such, JP '816 fails to disclose or suggest the methods of treating bacterial or viral infections with an extract of *Lentinus edodes* mycelium, and the invention of claims 26 and 27 is not anticipated by JP '816. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §102(e)

Claims 14-25 have been rejected under 35 U.S.C. §102(e) as being anticipated by Nagaoka U.S. '615. Claims 14-23 have been cancelled, thus rendering the rejection moot with regard to these claims. Applicants traverse the rejection of claims 24 and 25 and withdrawal thereof is respectfully requested. U.S. '615 is asserted to teach a composition produced in accordance with the present invention, which is used to treat tumors.

A full review of US '615 shows that the only disclosure in the reference with regard to treating tumors is the passing reference that the "cell wall lysis product-containing liquid (ii) contains β -glucan in high concentration shows excellent antitumor effects." See Abstract. However, this disclosure is based on a reported anti-tumor activity of β -glucan that is discussed in the "Background of the Invention", combined with the identification of β -glucan in the extract of the examples.

The inventors of the '615 patent did not actually test any antitumor activity of the extract obtained. In addition, there is no mention of activity of $\gamma\delta$ T cells in U.S. '615. The present invention specifically requires that the anti-tumor activity is from $\gamma\delta$ T cells.

In addition, the reported anti-tumor activity of β -glucan, that the inventors of '615 are relying on for the reference to anti-tumor activity is based on *in vitro* studies and with mouse xenoplated human tumors. No anti-tumor activity of β -glucan has been reported in *in vivo*. Further, the most accepted theory regarding the reported anti-tumor activity of β -glucan is that the antitumor activity of β -glucan is connected to humoral, i.e. antibody-mediated immunity, rather than T cell-mediated immunity.

Finally, Applicants note that the present invention specifically recites that the extract of *Lentinus edodes* mycelium used in the claimed method is made by digesting the *Lentinus edodes* mycelium with one or more enzymes selected from cellulose, protease and glucosidase. The method of producing β -glucan in US '615, on the other hand, uses "Fanselase", which is a cell wall lytic enzyme. (See Example 1) As such, the extract of US '615 is different from that of the instant invention and the instant invention is neither disclosed nor suggested by US '615. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §103

Claims 14-34 have been rejected under 35 U.S.C. §103 as being obvious over Nagaoka JP '070/U.S. '330, Nagaoka JP '816, and Nagaoka U.S. '615. The Examiner asserts that any

differences in the claims and the reference teachings reflect an obvious and conventional “result-effective” adjustment in the parameters of the prior art teachings. For example, the treatment of a particular virus or the use of particular formulations, the Examiner asserts are obvious modifications of the prior art teachings. Applicants traverse this rejection and withdrawal thereof is respectfully requested.

Contrary to the assertion of the Examiner the presently claimed methods differ from the disclosures in the references in more than obvious and conventional “result-effective” adjustment in the parameters disclosed in the references. As noted above, the invention of claim 26, and dependent claims thereon have been amended to exclude HIV as a viral infection to be treated. As further discussed above, HIV, being a retrovirus, has a very different life cycle from other viruses, such as hepatitis B. As such, the teachings of JP '070 are not predictive of the success of the claimed method. With regard to JP '816, as further discussed above, this reference does not pertain to treating infections but rather the altering melanin production. As such, JP '816 cannot be deemed to suggest the instant invention.

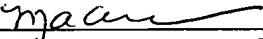
Similarly, the disclosure of the presence of β -glucan in the preparation of US '615, and the suggestion that β -glucan may have anti-tumor activity is not predictive or suggestive of the instant invention. As noted above, the preparation of US '615 and the extract of the instant claims are different and β -glucan is proposed to function through a different immune pathway than the present invention.

As such, the instant invention is not obvious over the cited references and withdrawal of the rejections is respectfully requested.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Dated: July 28, 2005

Respectfully submitted,

By 
Mary Anne Armstrong, Ph.D.
Registration No.: 40,069
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Rd
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicant